

# FISTULA CARE *PLUS* MEETING REPORT



Research consultation: Catheterization after obstructed labor  
July 17, 2015



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This report was authored by Vandana Tripathi and Celia Pett, with inputs from Lauren Bellhouse.

## Executive Summary

Despite strong interest in and some recommendations for urinary catheterization (UC) in the prevention of obstetric fistula following prolonged/obstructed labor (P/OL), there is no research evidence supporting its use. The *Fistula Care Plus* (FC+) project hosted a research consultation on July 17, 2015, to discuss the relevance, parameters, and feasibility of a study to evaluate the effects of UC in preventing obstetric fistula and/or related outcomes in immediate postpartum women after P/OL.

Meeting participants included FC+ staff, clinical and research experts, members of the FC+ International Research Advisory Group, and USAID representatives. Presenters summarized the current literature and evidence related to the study topic as well as key issues and challenges in study design. Participants discussed these topics, coming to a consensus on some and identifying key questions and next steps to address others.

A primary area of consensus among participants was the need for a survey of maternity service providers in FC+ countries and other settings where fistula is an important problem, to understand current practices related to UC after P/OL. This information will be crucial in assessing whether and how a research study can be implemented in an ethical and rigorous way to generate adequate clinical evidence.

Areas of agreement related to study design included the importance of clear case definition for P/OL given the dearth of consistent terminology and criteria across facilities and countries; the selection of voiding dysfunction (impaired bladder emptying) as the postpartum condition most likely to be implicated in fistula formation; and the importance of individual (vs. facility-level) randomization in generating valid evidence for the effects of UC.

However, there was considerable debate about other aspects of research such as inclusion/exclusion criteria, e.g., whether only women who have had vaginal deliveries in a facility should be eligible. It was also proposed that, given the absence of clinical evidence or information about UC practices after P/OL, a pilot study simply evaluating the feasibility systematic UC after P/OL could generate valuable evidence in settings where fistula is prevalent.

The meeting discussions and planned next steps are detailed in the report below. Appendices provide meeting materials and other resources.

## I. Meeting context and objectives

Urinary catheterization (UC) is an essential part of post-operative healing following surgical fistula repair. It has also long been thought to have an important role in the prevention and conservative treatment of fistula. Dr. Kees Waaldijk has reported that up to 25% of fresh fistulas between the bladder and vagina that are diagnosed acutely post-partum or, when iatrogenic, post-operatively, may be treated conservatively through UC alone, particularly with early management.<sup>1</sup> It has also been proposed that UC after prolonged/obstructed labor (P/OL) could prevent some fistula formation; this practice is included in clinical guidelines and curricula, for example from the World Health Organization (WHO)<sup>2</sup> and the East, Central, and South African Health Community (ECSA-HC).<sup>3</sup>

In 2013, the Fistula Care Project (FCP) convened a meeting in Nigeria to discuss the role of UC in fistula prevention and treatment.<sup>4</sup> Meeting participants recommended clinical algorithms for UC after P/OL to prevent obstetric fistula (see Appendix B). However, participants acknowledged the very limited clinical evidence supporting this practice.

In 2014, the Fistula Care *Plus* (FC+) project convened its International Research Advisory Group (IRAG) and other key partners to identify priority research topics related to obstetric fistula prevention and treatment, service delivery improvement, epidemiology, and community engagement.<sup>5</sup> Among clinical research topics, meeting participants selected research on the efficacy and effectiveness of UC for the prevention and conservative treatment of fistula as a very high priority. Participants noted that research into this topic could be particularly valuable as there are currently no evidence-based guidelines on proper bladder care before, during, or after labor. However, participants also recognized that research on this topic has been stymied by sample size considerations – tens of thousands of women with P/OL would be needed to adequately power a study with incidence of fistula as the outcome of interest. As a potential solution, it was suggested that a study of UC after P/OL could use incidence of bladder function/dysfunction as the outcome - this might reduce sample size; increase feasibility; and build evidence about the general science of bladder function, contributing to evidence-based guidelines for use in both developed and developing country settings.

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<sup>1</sup> Waaldijk K. The immediate management of fresh obstetric fistulas. *Am J Obstet Gynecol.* 2004 Sep;191(3):795-9.

<sup>2</sup> World Health Organization (WHO) Department of Reproductive Health and Research. 2000 (reprinted 2007). *Integrated management of pregnancy and childbirth. Managing complications in pregnancy and childbirth: A guide for midwives and doctors.* Available at: [http://www.who.int/maternal\\_child\\_adolescent/documents/9241545879/en/](http://www.who.int/maternal_child_adolescent/documents/9241545879/en/)

<sup>3</sup> East, Central, and Southern African Health Community (ECSA-HC) and Fistula Care/EngenderHealth. 2012. *The prevention and management of obstetric fistula: A curriculum for nurses and midwives.* New York: EngenderHealth/Fistula Care. Available at: [http://www.fistulacare.org/pages/pdf/Training/nursing\\_curriculum\\_2012\\_forweb.pdf](http://www.fistulacare.org/pages/pdf/Training/nursing_curriculum_2012_forweb.pdf)

<sup>4</sup> Fistula Care. 2013. *Urinary Catheterization for Primary and Secondary Prevention of Obstetric Fistula: Report of a Consultative Meeting to Review and Standardize Current Guidelines and Practices, March 13-15 at the Sheraton Hotel, Abuja, Nigeria.* New York: EngenderHealth/Fistula Care. Available at: <http://www.fistulacare.org/pages/pdf/program-reports/Catheterization-Fistula-Prevention-Meeting-Report-Nigeria-8-21-13FINAL.pdf>

<sup>5</sup> Fistula Care *Plus*/Maternal Health Task Force. 2014. *Fistula Care Plus: International Research Advisory Group Meeting Report, July 8-9, 2014.* New York: EngenderHealth/Fistula Care *Plus*.

However, there is considerable difference in the evidence generated by a study of fistula and one examining other outcomes. The relevance of other adverse outcomes to obstetric fistula prevention must be established, i.e., a plausible and clear physiological pathway linking bladder dysfunction and fistula formation. Additionally, numerous technical and practical study parameters and feasibility issues must be considered and addressed in order to conduct a rigorous study on UC, no matter which clinical outcome is selected.

Given the strong interest in evidence regarding UC for fistula prevention, FC+ convened a consultation on July 17, 2015 to discuss these topics and develop an action plan for research on the topic. The meeting agenda included presentation of current clinical evidence, discussion of key areas of debate in study design, and examination of specific study parameters to determine those with consensus and those that require further review. Overall, the meeting aimed to determine whether FC+ should invest resources in developing a study protocol on the effects of UC after P/OL and/or in gathering additional evidence to guide such a study.

Meeting participants included FC+ staff, clinical and research experts, IRAG members, and USAID representatives.

## II. Synthesis of relevant literature

To inform the discussion, Celia Pett presented a synthesis of current evidence related to UC after P/OL, as well as bladder dysfunction after P/OL. A synthesis of the relevant literature is provided here and citations for this section are given in Appendix C.

### A. Urinary catheterization after prolonged/obstructed labor

This literature search and synthesis reprises a review undertaken prior to the 2013 FCP meeting on UC. The search was updated for the 2015 consultation with a modified strategy and expanded search terms. The following search terms were used: UC; P/OL; prevention of obstetric fistula; and management of, guidelines for, indications for, intrapartum bladder care, postpartum bladder care. The terms were combined using the Boolean operator “and.” No limits were imposed on date, publication type, or study design and ‘grey’ literature, e.g. conference presentations, case studies, was included. Only English language publications were included. Abstracts and full text versions of articles were included. PubMed and Google were used to identify resources. Reference lists were scanned to identify additional potentially relevant publications.

A total of 26 relevant publications were identified and reviewed. Little new literature was identified compared to the 2013 search. Key findings are summarized here.

#### Definitions of prolonged/obstructed labor

There appears to be no consensus on the definition of P/OL. Numerous definitions were identified in the literature (ECSA-HC 2012, Kongnyuy et al. 2008, Neilson et al. 2003, WHO 2000, 2006, 2008, 2015). There is also a range of poorly defined associated terminology, such as “unsatisfactory progress of labor” and “delay in labor.” This presents an impediment to diagnosis and timely action, particularly important in the fistula context where laboring women often come to health facilities late and without any documentation relating to progress of labor. Notably, recent WHO recommendations on augmentation of labor (WHO/Jhpiego 2014) recognize the lack of consensus on the definition of “delay in labor” and variable definitions used in associated research. The WHO Guideline Development Group “agreed that adopting a specific definition for delayed labor might threaten the applicability of the guideline across all settings. Rather, the group emphasized that the standard that is followed should allow individual institutions or clinicians adequate time for clinical assessment and interventions (including referral) such that the desired benefits for both mother and baby can be achieved” (WHO/Jhpiego 2014).

#### Findings from literature on intrapartum and postpartum UC

No research studies were found on UC after P/OL. The few identified clinical guidelines and curricula on management of P/OL recommend immediate UC for women who have recently experienced P/OL (WHO 2000, WHO 2006, WHO 2008, ECSA-HC 2012). The key text on this subject is the WHO manual *Obstetric Fistula: Guiding principles for clinical management and programme development*, which recommends routine UC for 14 days plus a high fluid intake regime for all women immediately after P/OL “to try to prevent fistula” or to promote spontaneous closure of “very small fistulae” (WHO 2006). It also recommends that all maternity units should draw up a protocol for the management of women who have survived P/OL based on these principles. By contrast, the WHO *Integrated Management of Pregnancy and Childbirth*

manual on complications recommends UC for 48 hours after P/OL as part of its guidance on bladder care (WHO 2000/2007).

A number of articles, guidelines, and grey literature were identified on the topic of “best practices” for intrapartum and postpartum bladder care and UC. All were from high-income settings, mainly the United Kingdom (UK). The context is very different from countries where OL and obstetric fistula are prevalent; for example, much discussion centers on managing the effect of epidural analgesia on intrapartum and postpartum bladder function. However, some content is relevant. All the literature emphasizes the importance of intrapartum and postpartum bladder care and of documenting urine output during labor and after delivery. The recommended frequency of voiding in labor ranges somewhat arbitrarily from 2-6 hourly. The literature advises that women should be encouraged to void as soon as possible following delivery and that frequency of voiding be carefully monitored during the first 24 hours following delivery. Six hours postpartum is the generally cited threshold within which women are expected to pass urine successfully after vaginal delivery. After this, it is recommended that women are assessed and that UC should be considered or performed. Several sources, including two UK practice surveys (Carr and Cook 2013, Zaki et al. 2004) highlight a surprising lack of guidelines given the frequency of childbirth-related urological problems and recommend further research in order to develop evidence-based guidelines.

Intrapartum UC is discussed predominantly in relation to the effect of epidural anesthesia and preparation for operative vaginal delivery or C-section. Some articles voiced concern about possible iatrogenic injury arising from intrapartum UC and cautioned against ‘routine’ use of the procedure (Velinor 2010, Thrumurthy et al. 2010, Jansen et al. 2013). A 2014 Cochrane systematic review on indwelling bladder catheterization and C-section (Abdel-Aleem et al. 2014) was notable because it was the only resource that included research from low-income settings. Findings suggested that while UC was associated with less retention of urine after C-section, the resultant pain/discomfort, increased time to ambulate and hospital stay favored non-use of UC. However, these negative aspects may be of relatively less importance in the management of women who have survived P/OL.

It is significant that no peer-reviewed literature was identified on the postpartum care of women who have survived P/OL apart from the recommendations in the WHO manuals cited above (WHO 2006, WHO 2000/2007), a brief mention in *Practical Obstetric Fistula Surgery* (Hancock and Browning 2009), and the recommendations in the FCP supported ECSA-HC curriculum on prevention and management of obstetric fistula (ECSA-HC 2012). The other texts on management of P/OL (Kongnyuy 2008, WHO 2000, WHO 2008) describe intrapartum management up to operative vaginal delivery or C-section, but include no specific guidance on postpartum care.

The few guidelines identified for intrapartum bladder care and UC are prescriptive but provide scant explanation of the physiological mechanisms or evidence to support their recommendations. Most simply state that the bladder is usually hypotonic after P/OL (and after regional anesthesia and C-section) and that it is important to avoid bladder over-distension because this can cause permanent damage to the detrusor muscle and continence mechanisms.

## B. Bladder dysfunction after obstructed labor

The following search terms were used: postpartum bladder dysfunction, postpartum pelvic floor dysfunction, postpartum voiding dysfunction, P/OL. The terms were combined using the Boolean operator “and.” Resources on postpartum fecal incontinence and adult female urinary incontinence were excluded and the review was limited to English language texts. No date restrictions were applied. PubMed and Google were used to identify resources. A total of 34 relevant publications were identified and reviewed. Given time constraints and the large body of literature on this subject, this search was primarily limited to review of abstracts. However, several full-text journal articles, which appeared to be of particular relevance, were also included. This search therefore provides only a “snapshot” of existing literature and is not exhaustive. All the literature identified was from high-income settings.

### Terminology report

It is important to note that this synthesis emphasizes the research evidence published in peer-reviewed journals and highlights an absence of consistent terminology and precise definitions. However, a terminology report has been published by the International Urogynecology Association (IUGA) and the International Continence Society (ICS) (Hayden et al. 2010). This report provides consensus-based terms and definitions for a number of the topics discussed below, notably voiding dysfunction (and the related broader term “lower urinary tract symptoms”) and stress incontinence.

### Postpartum voiding dysfunction (PVD)/postpartum urinary retention (PUR)

The terms “postpartum bladder dysfunction,” PVD, and PUR appear to be used synonymously in the peer-reviewed literature. PUR was commonly defined as “the inability to pass urine spontaneously within 6 hours of delivery or following catheter removal after delivery” (Kearney and Cutner 2008). Persistent (or protracted) PUR was defined as “the inability to void spontaneously beyond the third postpartum day” (Kearney and Cutner 2008, Groutz et al. 2001, Groutz et al. 2011, South Australia DOH 2012). PUR was defined as either “overt,” i.e., inability to pass urine after delivery; or “covert,” i.e., elevated post-void residual urine volume >150 mL with no symptoms of urinary retention. Kearney and Cutner (2008) asserted that studies assessing the effects of covert PUR have not established an increased risk of future urinary problems. Estimates of the incidence of PUR ranged from 0.05 – 37% (Leach 2011, Lim 2010, Saultz et al. 1991). This wide range is thought to be due to the variety of definitions of PUR in different studies (Lim 2010).

An additional research study, brought to attention during the FC+ meeting, suggests that protracted labor longer than or equal to 800 min (>13 hours) is associated with a higher incidence of PUR (Yip, Hin and Chung 1998).

Reported risk factors for postpartum bladder dysfunction, specifically PUR, included:

- History of voiding difficulties
- Primiparity
- First vaginal birth

- Oxytocin and prostaglandin use
  - Epidural, spinal or pudendal anesthesia
  - Difficult instrumental birth and/or shoulder dystocia
  - Cesarean section
  - Prolonged labor
  - Birth weight of > 3.8 kg
  - Excessive perineal trauma
  - Catheterisation during or after birth
- (Groutz 2001, Kearney and Cutner 2008, Leach 2011)

The literature emphasized the importance of early diagnosis and treatment with UC, antibiotics if necessary to treat urinary tract infection, and follow-up assessment if voiding dysfunction persists. The objective of treatment by UC (indwelling or intermittent self-catheterization) is to avoid over-distension of the bladder, which can result in severe detrusor muscle damage and may lead to permanent urinary problems (Kearney and Cutner 2008). A 2011 study reported that 55 women (0.18%) of a study population of 30,757 women delivering in a hospital setting developed protracted PUR (Groutz 2011). With early diagnosis and UC treatment, all returned to “normal bladder function” within 28 days. However at follow-up (3-39 months), 5 (10.4% of those with PUR) reported stress urinary incontinence (SUI) and 4 (8.3%) had overactive bladder symptoms. Several sources recommended that all units should have a protocol for bladder care and management of PUR/PVD, citing low awareness of PUR in maternity units as a major barrier to implementation of existing guidelines (Humburg 2008, Kearney and Cutner 2008). Two practice guidelines identified included a treatment algorithm for management of PUR/PVD (Kearney and Cutner 2008, South Australia DOH 2012)

None of the literature defined the term “normal bladder function” or specified a typical length of time for return to normal bladder function postpartum. However, a 2011 consensus statement from the US on “healthy bladder functioning” developed by a panel of clinical experts stated:

*A healthy bladder is free of bacterial infection or tumors and stores urine without discomfort at low pressure with intermittent signals of filling. Normal functional bladder capacity in adults ranges from approximately 300 to 400 ml. Although the International Continence Society defines urinary frequency as the perception by the patient that he/she voids too often, epidemiological studies suggest that the normal micturition rate is approximately 8 micturitions per day and 1 or fewer episodes per night. (Lukacz 2011)*

There appear to be little data on long-term sequelae of PUR (Humburg 2008). It is suggested that protracted PUR may be associated with long-term bladder dysfunction (Groutz et al. 2001).

#### Pregnancy and postpartum stress incontinence

The term ‘stress incontinence’ is not defined in the peer-reviewed literature identified. A review of prevalence and incidence of childbirth-related incontinence in Europe (Cerruto et al. 2013) stated that variations in definition, outcome measures, survey methods and validation criteria make it impossible to draw definitive conclusions. Prevalence estimates SUI in pregnancy ranged from 18.6% - 75% (Cerruto et al. 2013, Sangsawang 2014). Prevalence was said to

increase as pregnancy advances. Physiological changes, such as increasing pressure of the growing uterus and fetal weight on the pelvic floor muscle (PFM) throughout pregnancy, together with changes in hormone levels, such as progesterone, relaxin, and collagen, may lead to reduced PFM strength and competence of the urethral sphincter (Sangsawang and Sangsawang 2013). Additional risk factors cited were maternal age above 35 years, obesity and a family history of SUI (Cerruto et al. 2013, Sangsawang 2014). One systematic review of population-based studies on postpartum SUI was identified (Thom et al. 2010). Pooled prevalence (up to 1 year postpartum) was 33%, although prevalence of SUI after C-section was half that after vaginal delivery.

Two reviews posit that SUI in pregnancy and a family history of SUI may be risk factors for postpartum and/or longterm SUI (Cardozo et al. 1997). A study of 549 nulliparous women (Chaliha et al. 1999) assessed whether physical markers of collagen weakness (e.g., striae) could predict postpartum incontinence. However, the physical markers in this study could not predict postpartum urinary or fecal incontinence.

#### Pelvic floor dysfunction (PFD)/effect of pregnancy and childbirth-related pelvic floor trauma

The majority of reviews identified addressed PFD, which is a very broad term not clearly defined in the resources. No prevalence estimates were provided. All reviews acknowledge that pregnancy and childbirth inevitably result in some degree of damage to the pelvic floor. The main debate concerned the clinical significance of this damage in the pathogenesis of incontinence and prolapse in later life and the extent to which elective C-section is protective (Chaliha 2009, Dietz and Wilson 2006, Panayi and Khullar 2009, Rogers and Leeman 2007, Turner 2009). Several sources concluded that although elective C-section reduces pelvic floor trauma, the protective effect is limited and should be weighed against the cost and risk of C-section (Dietz 2005, Herbruck 2008). There is a call for more research to compare the effect of pregnancy and different modes of delivery (vaginal, CS: labored and unlabored) on PFD (Chaliha 2009, Rogers and Leeman 2007). An additional recent research study on female rats was brought to attention during the FC+ July 2015 consultation, which suggested that pelvic crush injury (plausibly similar to the effect of obstructed labor) caused reduced genital blood flow and resulted in vaginal fibrosis (Castiglione et al. 2015).

A “non-systematic” review of evidence on the effect of racial background on the epidemiology and pathophysiology of pelvic floor dysfunction found that white women are at increased risk of SUI, but that there is insufficient evidence to draw conclusions regarding the role of racial differences in pelvic organ prolapse (Kim, Harvey and Johnston 2005).

### III. Illustrative study design

Dr. Michel Boulvain presented a research protocol he developed in the 1990s for a randomized-controlled trial (RCT) to evaluate the effects of postpartum UC after OL in preventing obstetric fistula. Dr. Boulvain explained that the idea for this study arose from his experiences working as an obstetrician in Benin as well as guidance in a seminal textbook on obstetrics in developing countries.<sup>6</sup> While the study was not funded and implemented, Dr. Boulvain's protocol remains the only in-depth (beyond concept paper) treatment of this research topic that FC+ has been able to identify.

The original protocol called for a cluster-randomized (i.e., facility-level randomization) trial building on a pilot survey of provider practices. The protocol envisioned enrolling women admitted in OL or within 24 hours postpartum. The intervention was planned to be 10 days of UC following OL. Obstetric fistula was to be diagnosed at 10 days or discharge using vaginal examination and dye test if needed. The protocol provided case definitions for OL and other inclusion/exclusion criteria for facilities and women.

In his presentation of the proposed research design, Dr. Boulvain identified several issues that require further discussion and decision-making if a study is to be implemented today:

- *Definition of OL used for case identification:* Dr. Boulvain noted that there must be comparable severity of OL cases in both study arms, and that OL might be defined through duration of labor but also signs (e.g., caput, Bandl's ring) and/or stillbirth.
- *Ascertainment of lower urinary tract fistula:*<sup>7</sup> Dr. Boulvain noted that a dye test at discharge is the simplest to apply across patients (vs. dye test 3 months after discharge), and that complete continence and restored bladder function would be difficult to assess, requiring a strong definition. The timing of fistula ascertainment was also discussed; while assessment several months after discharge would be ideal, follow-up challenges might preclude this.
- *Duration of postpartum UC:* Dr. Boulvain suggested that a shorter (7 day) regimen may be optimal, in line with the FCP RCT on UC following fistula repair, possibly with an option for catheter removal upon examination at 3 days.
- *Level of randomization:* Dr. Boulvain discussed the pros and cons of individual randomization, noting the risk of contamination but the advantages in terms of power and sample size.

Participants raised several issues during discussion:

- There is likely to be large variation in current practices in UC and a lack of standard protocols at many facilities.
- FCP experienced very high follow-up (e.g., 96% in the RCT) in its clinical studies; however, there may be differences in retention among those receiving fistula treatment and those who have survived P/OL.

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<sup>6</sup> Lawson JB, Steward DB. 1967. *Obstetrics and Gynaecology and the Tropics and Developing Countries*. London: Edward Arnold.

<sup>7</sup> Dye (blue) tests are negative with upper tract (ureteric) fistula.

- It may be useful to retain the definition of OL used in criteria-based audit studies in Malawi (Kongnyuy 2009).
- Prior FCP studies provide lessons in “community building” and promoting adherence to protocols by participating providers. In defining P/OL and determining UC regimens, it would be useful to have formative discussions with local providers. This will make it easier to ask providers to change their management practices “for the purposes of the study” and ensure better standardization/compliance during research.
- Because a study on UC following P/OL involves (in many facilities) implementing an intervention that didn’t exist before, it is important to include secondary outcomes on safety.

## IV. Discussion of study parameters and feasibility

### A. Changing the outcome: obstetric fistula vs. bladder dysfunction

The motivation for changing the primary outcome in a UC study from obstetric fistula to bladder dysfunction is the reduction in sample size. Applying the assumptions presented in a 2003 WHO analysis of OL and its sequelae,<sup>8</sup> an individually-randomized study using fistula as the outcome would require thousands of women with P/OL to be enrolled (Table 1). These sample sizes may need to be adjusted upward, since the incidence of fistula following P/OL in a facility would be expected to be much smaller than the incidence following P/OL without management with skilled emergency obstetric care. Additionally, assuming that 5% of deliveries result in OL, this requires that 20 times as many deliveries be monitored to identify an adequate number of cases, before applying any other inclusion/exclusion criteria. In contrast, bladder dysfunction (e.g., stress incontinence, voiding impairment, or other problems) is likely to be much more common following P/OL, as evidenced in the literature synthesis above. Table 2 shows the dramatic impact on sample size if bladder dysfunction is used as the outcome of interest.

Table 1: Estimated sample sizes, fistula as outcome of interest

Incidence in comparison group (fistula)	Relative risk (treatment effect of catheterization) with power (1-β) – 0.8			
	0.8	0.75	0.6	0.5
0.05	13,490	8,404	3,012	1,812
0.03	22,910	14,266	5,106	3,068
0.02	34,682	21,590	7,722	4,638

Table 2: Estimated sample sizes, bladder dysfunction as outcome of interest

Incidence in comparison group (bladder dysfunction)	Relative risk (treatment effect of catheterization) with power (1-β) – 0.8			
	0.8	0.75	0.6	0.5
0.25	2,188	1,372	500	304
0.20	2,894	1,812	658	398
0.15	4,072	2,544	920	556

Despite the practical advantage of using bladder dysfunction as the outcome of interest, there are important questions to be considered before endorsing such a shift: 1) Is bladder dysfunction clinically relevant to fistula formation; and 2) How should bladder dysfunction be defined in a study of UC after P/OL?

<sup>8</sup> Dolea C and Abou Zahr C. 2003. *Global burden of obstructed labour in the year 2000*. Geneva: World Health Organization/Evidence and Information for Policy.

Consultation participants discussed these questions, keeping in mind that, whatever the clinical interest in evidence regarding bladder dysfunction in and of itself, there must be a clear and strong applicability to obstetric fistula prevention for FC+ to directly conduct such research.

Participants discussed whether a study finding association between UC after P/OL and bladder dysfunction would have plausible inference for fistula prevention programs; e.g., could bladder dysfunction be treated as an intermediate outcome denoting significantly increased fistula risk? First, the two mechanisms by which UC might have an effect on fistula were reviewed: 1) by promoting the closure of fresh fistula, and 2) by relieving tension on the bladder due to urine retention. Given this meeting's focus on prevention, the second pathway was the primary discussion point. Participants generally felt that this pathway was plausible: voiding dysfunction, i.e., impaired bladder emptying, could lead to increased urine retention and pressure on the bladder, which could lead to tissue ischemia and fistula formation. However, it was noted that plausibility among a group of urologists and urogynecologists is not identical to perceived relevance among wider readers, including funders who may need to see a clearer link to fistula. Envisioning the publications that could result from the research under consideration, a participant noted that research conducted by FC+ must have implications for fistula prevention and treatment that are not "hidden away in the discussion," but that "rise to the level of the abstract, firmly stated."

Some participants also noted that, given a lack of published evidence about the physiological pathways discussed, it might be useful to generate basic information, e.g., through a "Phase II" study of mechanisms of action. However, other participants pointed out existing research evidence (including in animal models) on the relationship between voiding dysfunction and ischemia, suggesting that there is adequate clinical evidence to justify inferences about fistula prevention **if** the appropriate type of bladder dysfunction is assessed. Participants additionally suggested that research using a proxy outcome has value because widely circulated guidelines are advocating for UC after P/OL in the absence of any clinical research evidence.

Participants then discussed how to define bladder dysfunction for a study of UC after P/OL that would have strong relevance for fistula prevention. There was agreement that one specific outcome should be selected, vs. a composite outcome including different types of dysfunction. Participants agreed that, given the physiological pathway discussed above, the outcome should be voiding dysfunction. This is most appropriate as a proxy outcome: it is plausible as an intermediate step on the route to fistula formation and, therefore, as a marker of increased fistula risk.

However, there was considerable uncertainty about the precise definition of voiding dysfunction; acceptable thresholds are also measurement-dependent (i.e., via transvaginal ultrasound vs. catheterization). There was also discussion about the time point following delivery at which this outcome would first be diagnosed. Six hours was suggested, given the literature presented by Ms. Pett; however, that literature is primarily based on developed country settings. Finally, there also uncertainty about whether voiding dysfunction should be assessed at baseline before UC or only after catheter removal.

## B. Other study parameters

Whatever outcome variable is selected, developing a valid study of UC after P/OL also requires decision-making regarding many other aspects of study design. Study participants discussed a number of such questions, as summarized here:

- *What is a reasonable expectation for the effect of UC on the outcome(s) of interest?*

Sample sizes in Tables 1 and 2 were calculated using a range of effect sizes centered on the 25% treatment success rate estimated by Waaldijk in conservative treatment of fresh fistula through UC, described in Section I. However, the physiological mechanism for conservative treatment is quite different from that expected to support UC for prevention (see Section IV.A.). Therefore, there is no guidance for estimated effect size. Instead, it may be more useful to power a study (i.e., set its minimal sample size) based on the effect size that would be required to be clinically meaningful – the level at which clinicians could ethically introduce an intervention with cost implications (e.g., increased duration of inpatient care) and potential adverse effects (e.g., infections) to women who have already experienced difficult birth, in low-resource settings. Participants noted that the effect size would need to be higher if the study outcome was bladder dysfunction, since this is much less severe than fistula and not all cases of voiding dysfunction would result in fistula.

- *What is the appropriate duration of UC in the intervention arm?*

Participants discussed the rationale for different lengths of UC. A possibility is 14 days, based on the recommendation in the WHO fistula manual. On the other hand, this may be an unrealistic length of time to expect women to remain in a busy facility after delivery. Other participants suggested that 3 days be tested, as a more realistic intervention. Most participants felt that it would be useful to know the range of current practices before selecting the duration of UC.

- *What are appropriate settings for such a study?*

Participants agreed that the study should not be restricted only to countries with current policies regarding UC after P/OL or vice versa, or only to facilities where current UC practices are above or below certain threshold levels. It was felt that such restrictions would introduce confounding factors that could severely limit the validity and generalizability of any findings. Participants also generally agreed that the study should be conducted in multiple sites, to promote both feasibility (i.e., identification of adequate numbers of P/OL cases) and face validity (i.e., perception among clinicians that findings are relevant to their settings). However, there were questions about the appropriate types of facilities. For instance, participants felt that the study should not be conducted in low-level facilities, for practical reasons as well as to ensure adequate clinical capacity. However, there were also concerns about extremely high-level facilities, where obstetric care providers are overwhelmed and it could be hard to take on a research activity. There was a consensus that ideal facilities would be, in the words of one participant, “at the high end of medium.”

- *Should randomization be at the facility or individual level?*

Participants felt strongly that randomization should be at the individual level, as facilities could vary in important ways. Individual randomization would also avoid sample size increases

associated with facility-level (cluster) randomization. Participants felt that risks of contamination with individual randomization could be mitigated in the design and orientation phase.

- *What are appropriate individual-level inclusion/exclusion criteria?*

Participants discussed eligibility criteria in terms of internal and external validity. For instance, it was suggested that enrollment criteria must not be so exclusionary that providers would feel findings could not be applied in broader practice. Inclusion/exclusion criteria discussed included:

- Only those delivering vaginally? Or C-section also?
  - o In settings where few deliver in facilities unless complications arise, would eliminating C-sections eliminate too many P/OL cases?
- Only those without fistula on baseline exam?
- Only those without intrapartum UC?
- Only those with a threshold level baseline (immediate/6 hrs postpartum) urine output?
- Only those delivering in a facility? Or presenting within a certain time after delivery? Or screened in the community and identified as having experienced P/OL?
  - o Is facility labor a proxy for P/OL severity in settings where, again, women don't generally seek care unless complications arise?
- Only those with a certain level of P/OL severity?
  - o How does this intersect with inclusion/exclusion of those with C-sections? Restriction to vaginal delivery might imply restriction to "mild" P/OL; therefore including only vaginal delivery **and** only severe P/OL cases might make adequate enrollment numbers impossible.
- Only those who consent to return for follow-up at a certain number of weeks/months postpartum?

There was no consensus among participants on inclusion/exclusion. However, it is important to note feedback on three topics:

- Since intrapartum UC is recommended in much current clinical guidance regarding P/OL (albeit without strong evidence), it was felt that excluding those who had been catheterized during labor would eliminate the possibility of a comparison group. Participants then discussed whether, among those with intrapartum UC, the study could randomize participants to have the catheter removed or retained as the intervention (vs. insertion of catheter). The effect of intrapartum UC on the ability to establish baseline voiding capacity (before insertion of postpartum catheter) was also discussed.
- At least half of the participants felt that it would be optimal to exclude those who had C-section if it was possible to do so without drastically affecting enrollment rates and, thus, feasibility.
- Finally, participants agreed that there was an important distinction between a study of fistula prevention and one of conservative treatment with UC. Given the complete lack of information on prevention and greater number of P/OL cases than fresh fistula cases, participants agreed that an RCT study must focus on prevention. This means that only women who do not have fistula upon exam immediately postpartum should be included in a study of the effectiveness of UC for fistula prevention. However, participants felt very strongly that it would be important to provide treatment via UC to those diagnosed with fresh fistula even if they are not included in a "main study," and that they should be closely monitored with outcomes documented. Those with not-closed fistulas should be referred for surgical treatment when appropriate. This would enable a study of conservative treatment to be embedded in a main study, although without the

power to draw inferences with statistical significance. Embedding such a study is an opportunity to replicate the Waaldijk findings regarding conservative treatment and, most importantly, ensure that all those with fistula receive adequate treatment. Related to this, participants also noted that any research on UC introducing systematic examination for fistula after P/OL would be valuable, as even this basic practice is not conducted consistently in relevant clinical settings.

Given the disagreement and uncertainty on many of these study parameters, it was strongly recommended that all decisions related to study aims and design be carefully documented in an issues log, such as that utilized by the FCP RCT on duration of UC after fistula repair.

## **C. Sites, partners, and funding**

The discussion of potential sites, partners, and donors was relatively brief. Participants suggested that a list of potential study sites should begin with those where FCP or FC+ has supported improved delivery care. However, it was noted that the FCP RCT included countries where FCP was not working, even those where USAID was not supporting bilateral fistula activities. Participants suggested that, should FC+ proceed to protocol development for a study of UC after P/OL, it would be important to include partners such as WHO; UNFPA and the Campaign to End Fistula; ECSA-HC; and the Royal College of Obstetricians and Gynaecologists (RCOG), which has also been considering how to implement research on fistula prevention through UC.

Finally, the only funders beyond USAID suggested for approach with a study concept or protocol were the Bill and Melinda Gates Foundation and the National Institutes of Health.

## V. Action steps and conclusions

### A. Survey of practices

As noted above, participants did not come to a consensus on many study parameters. However, there was unanimous agreement that more information on current practices would guide numerous aspects of study design, as well as helping to determine the pragmatic value of a randomized RCT vs. of types of research (e.g., case series, case-control study, operations research). Given the dearth of information and guidance on postpartum care after P/OL, a survey of practices would in itself be a valuable contribution to the field.

Therefore, it was recommended that FC+ should conduct a survey of clinical practices after P/OL in FC+ countries and other settings where obstetric fistula is considered to be a problem.

Participant recommendations for the design of such a survey include:

- Target a range of maternity care cadres, including through midwifery associations as well as OB-GYN associations.
- Include policy-level stakeholders and oversight cadres (e.g., provincial medical officers or regional supervisors) as informants in generating a survey sample and obtaining any relevant policy guidance.

Participants discussed the importance of obtaining responses from “typical” providers and not merely those most likely to be adherent to guidelines (e.g., academic clinicians) or those invested in demonstrating adherence to such guidelines (e.g., regional supervisors).

### B. Other areas of consensus

While many issues remained “unsettled” following discussion, there were several areas of consensus related to a research study, including the importance of:

- Providing a clear case definition for P/OL given the dearth of consistent terminology and criteria across facilities and countries.
- Selecting voiding dysfunction as the postpartum condition most likely to be implicated in fistula formation and, thus, the best candidate for a proxy/intermediate outcome.
- Including secondary outcomes related to safety (e.g., infections).
- Monitoring obstetric fistula incidence, should the primary outcome be an intermediate condition like voiding dysfunction.
- Using individual (vs. facility-level) randomization.
- Ensuring that all women diagnosed with “fresh fistula” receive UC and referral for additional care, if needed, with rigorous documentation of outcomes.

## C. Alternate research direction

Participants expressed concerns about the sample sizes required to conduct an RCT on UC after P/OL even with a proxy outcome, particularly given the limited amount of time available to conduct such a study in the FC+ project lifespan. Related feasibility challenges were identified that could affect the likelihood of generating robust evidence through an RCT, including:

- The difficulty of identifying an adequate number of facility-based P/OL cases severe enough to create a risk of fistula or serious voiding dysfunction, but delivered vaginally.
- The potential confounding effects of intrapartum UC.
- The feasibility of identifying women willing to receive UC and remain under inpatient observation after P/OL.
- The feasibility of devoting hospital resources to 2-14 days of UC in settings where there is already a strain on beds and providers.

Given these challenges, some participants suggested that, rather than embark on a full-scale RCT, it would be useful to conduct a pilot feasibility study, focusing on the ability of a representative health facility (or several facilities) to consistently identify P/OL cases, conduct adequate baseline and post-UC assessment of voiding dysfunction and safely implement postpartum UC without adversely affecting the volume and quality of maternity services.

While such a study would not generate statistically significant, experimental evidence about the efficacy of UC in preventing obstetric fistula or voiding dysfunction, it might provide valuable information, particularly since existing guidelines are advocating for different durations of UC after P/OL with almost no information on its feasibility and acceptability to women and clinicians.

## D. Other recommended actions

Participants also recommended that FC+, while considering directions for research activity, take the following actions:

- Share the literature synthesis with the WHO Reproductive Health and Research division and actors such as IUGA/ICS, noting the conflicting recommendations related to duration of UC after P/OL and the lack of evidence for these recommendations.
- Conduct a focus group or discussion regarding UC practices at upcoming events including the September 2015 FC+ meeting on integration of prolapse and other services with fistula care, and the FIGO World Congress and Global Maternal and Newborn Health Conference in October 2015.

## E. Conclusion

This research consultation underscored the need for more information about UC after P/OL in settings where obstetric fistula remains prevalent. The discussion identified several directions for evidence generation that can be undertaken by FC+ and other partners in the fistula prevention and treatment communities.

However, the meeting discussion showed clearly that there is no ideal first study on UC after P/OL. No single study design can optimize evidence generation both on efficacy and effectiveness or both internal and external validity. For example, a study that is “pure” in its participant selection, including only those who have severe P/OL, vaginal delivery in the hospital setting, and no experience of intrapartum UC, would be so narrow as to eliminate generalizability and, thus, the potential for clinical extrapolation. Such a study would also likely be unable to identify and enroll a sufficient number of women. Therefore, any research undertaken by FC+ will be an important starting point in understanding the role of UC in fistula prevention and more generally in postpartum care after P/OL. This will be a valuable contribution given the current absence of clinical evidence, but will likely not “settle” questions related to mechanism of action or scaled-up implementation.

## Appendix A: Meeting agenda and participants

### AGENDA

Time	Session	Presenter/Facilitator
8:30am	Breakfast	
9:00am	1. Welcome, introductions, and review of meeting aims	Lauri Romanzi
9:15am	2. Proposed study in the context of FC+ research agenda	Vandana Tripathi
9:30am	3. Synthesis of relevant literature/evidence	Celia Pett
10:00am	4. Presentation of illustrative study design	Michel Boulvain
10:30am	5. Debate 1: Defining the outcome of interest – incidence of fistula vs. bladder dysfunction/return to normal function. <i>What is the impact on study relevance and value?</i>	Lauri Romanzi
12:00pm	Lunch – provided at EngenderHealth	
1:00pm	6. Debate 2: Defining the intervention and comparison arms. <i>The problem of 'clean controls' in a context of variable practices after obstructed labor</i>	
1:30pm	7. Study parameters: Participants/eligibility, assignment/randomization level, sample sizes	Mark Barone
2:30pm	Break	
2:45pm	8. Study feasibility: Partners, possible sites, funding	Lauri Romanzi
3:30pm	9. Wrap-up: Next steps, participant roles	Vandana Tripathi

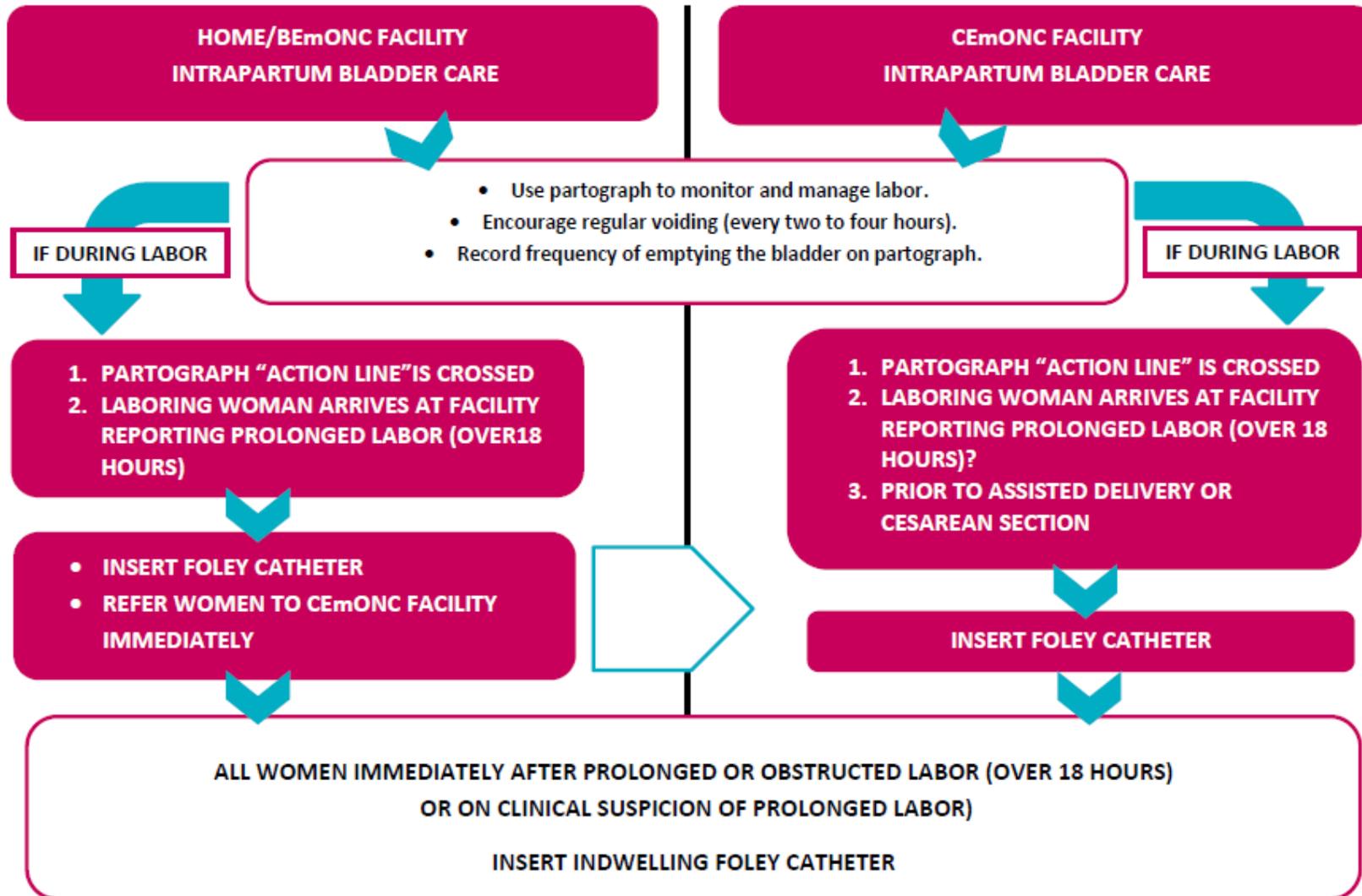
### PARTICIPANTS

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Suzy Elneil, FIGO*
Vera Frajzyngier, Pfizer, Inc.
Erin Mielke, USAID*
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Mary Ellen Stanton, USAID
Vandana Tripathi, FC+

\*Participating remotely

## Appendix B: Fistula Care Project algorithm for catheterization after obstructed labor

### A: Flow chart: Urinary catheterization to prevent obstetric fistula



## B: Recommendations for Guidelines for Urinary Catheterization to Prevent Obstetric Fistula

<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>Client has assisted delivery or cesarean section.</li> <li>Labor lasts over 18 hours or the partograph "action line" is crossed.</li> <li>Client presents immediately after prolonged or obstructed labor.</li> </ul>	
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>After appropriate counseling, client refuses treatment</li> <li>Bladder carcinoma (very rare)</li> </ul>	
<b>Responsibility for catheterization insertion and management</b>	Insertion, management, assessment of progress and removal may be performed in the community (including at home), first-level facility, or CEmONC facility by any trained provider, clinically competent and authorized: <ul style="list-style-type: none"> <li>To conduct deliveries</li> <li>To insert a urinary catheter</li> </ul>	
	<b>HOME/BEmONC FACILITY</b>	<b>CEmONC FACILITY</b>
<b>Suggested management protocol</b>	<ul style="list-style-type: none"> <li>Use partograph to monitor labor.</li> <li>Encourage regular voiding (every two hours).</li> <li>Record frequency of emptying the bladder on partograph.</li> <li>Have competent provider insert Foley catheter (size 16–18) at home or first-level health facility prior to emergency referral.</li> <li>Detect prolonged or obstructed labor early and refer to CEmONC facility.</li> </ul>	<ul style="list-style-type: none"> <li>Use partograph to monitor labor.</li> <li>Encourage regular voiding (every two hours).</li> <li>Record frequency of emptying the bladder on partograph.</li> <li>Insert Foley catheter prior to assisted delivery/CS.</li> <li>Follow protocol immediately after delivery for all women experiencing prolonged or obstructed labor.</li> </ul>
<b>Observations while catheter is in situ</b>	The following observations should be made every four hours for 24 hours post natally and then daily: <ul style="list-style-type: none"> <li>Haematuria</li> <li>Cloudy or purulent urine</li> <li>Urine output</li> </ul>	
<b>Ancillary treatment</b>	<ul style="list-style-type: none"> <li>Antibiotics only if clinically indicated for infection</li> <li>High fluid intake regime: 5–8 L per day</li> </ul>	
<b>Prior to catheter removal</b>	<ul style="list-style-type: none"> <li>Perform pelvic examination.</li> <li>Retain catheter if there is clinical suspicion of fistula and refer to facility with fistula expertise.</li> </ul>	
<b>Predischarge counseling</b>	<ul style="list-style-type: none"> <li>Counsel client to return immediately to facility in case of leaking urine.</li> <li>Provide family planning counseling, including information on contraception and birth spacing.</li> </ul>	
<b>Follow-up</b>	Fit into postnatal visit schedule based on national policy.	
<b>Recommended program indicators</b>	<ul style="list-style-type: none"> <li>Availability of protocol at all facilities</li> <li>Number of providers trained and competent in partograph use and catheter insertion and management</li> <li>Number of women in prolonged or obstructed labor who were catheterized according to protocol compared to number of women admitted with prolonged or obstructed labor</li> <li>Establishment of routine clinical audit process at all facilities for women who have experienced prolonged or obstructed labor and frequency of clinical audit</li> </ul>	
<b>Implementation challenges</b>	<ul style="list-style-type: none"> <li>Many women come late in labor, limiting effectiveness of facility-based labor monitoring and decision making.</li> <li>Major systems challenges to implementation include sufficient skilled staff, resources, logistics, bed space, and supplies.</li> </ul>	

Source: Fistula Care. 2013. *Urinary Catheterization for Primary and Secondary Prevention of Obstetric Fistula: Report of a Consultative Meeting to Review and Standardize Current Guidelines and Practices, March 13-15 2013*, at the Sheraton Hotel, Abuja, Nigeria. New York: EngenderHealth/Fistula Care.

## Appendix C: Citations for evidence synthesis

### A. CATHETERIZATION AFTER PROLONGED/OBSTRUCTED LABOR

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## **B. BLADDER DYSFUNCTION AFTER PROLONGED/OBSTRUCTED LABOR**

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